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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,119	07/16/2003	Arthur E. Quaid	MAKO 2 00027-3	9089
27885	7590	02/03/2010		
FAY SHARPE LLP 1228 Euclid Avenue, 5th Floor The Halle Building Cleveland, OH 44115			EXAMINER CHAO, ELMER M	
			ART UNIT 3737	PAPER NUMBER
			MAIL DATE 02/03/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/621,119

Applicant(s)

QUAID ET AL.

Examiner

ELMER CHAO

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12, 13, 15-19, 21-27, 30, 32-40, 42, 43, 46-49, 52-55, 57, 58, 61-64, 66, 67, 70-72, and 74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-646)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims pending in the application are 1-10,12,13,15-19,21-27,30,32-40,42,43,46-49,52-55,57,58,61-64,66,67,70-72 and 74.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/13/2009 has been entered.

Claim Objections

2. **Claims 2-9 and 13** are objected to because of the following informalities:

Regarding **claim 2**, line 7, the limitation "object, which anatomical object has" should instead read "object, in which the anatomical object has".

Appropriate correction is required.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. **Claims 66, 67, 70-72, and 74** are rejected under 35 U.S.C. 101 because the state-of-the-art in the field of computer readable media suggests that a computer readable medium can take both tangible forms and non-tangible or transitory forms

(such as signals and carrier waves). Since the broadest reasonable interpretation of the limitation "computer readable medium" not only takes into account the disclosed invention but also the level of skill in the art, it would be reasonable to conclude in this case that the claim is broad enough to read on both a statutory and non-statutory embodiment.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 1-7, 9, 10, 12, 13, 15-19, 32-38, 40, 42, 43, 46-48, 66, 67, and 70** are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. (U.S. 5,950,629) in view of Niemeyer et al. (U.S. 6,424,885 B1).

Regarding **claims 1-5, 9, 10, 12, 13, and 17-19**, Taylor et al. teach a method for use of a computer-assisted surgery system during a medical procedure, comprising: receiving information on an anatomical target region of a patient (col. 20, line 22—col. 21, line 16); tracking the position of a manually manipulatable tool mechanically coupled to a haptic device as a surgeon manually manipulates the tool (col. 20, line 22—col. 21, line 16; col. 15, lines 8-35; col. 16, lines 34-67); determining a scalar distance between a current position of said tool and the anatomical target region (col. 13, lines 45 - 52).

Taylor et al. teach the limitations as discussed above but fail to explicitly teach the surgery used for removing tissue. However, Taylor et al. do teach using cutting instruments with the haptic device (col. 18, lines 27-53). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Taylor et al. to remove tissue as it is a design choice that is performed by the necessity of a chosen surgical operation.

Taylor et al. teach the limitations as discussed above but fail to explicitly teach the object of interest being at least one haptic virtual object that represents a virtual cutting boundary of the tool. However, in the same field of endeavor, Neimeyer teach an object of interest being at least one haptic virtual object for surgery (col. 31, line 58-67). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to include at least one haptic virtual object that represents a virtual cutting boundary for the tool in order to prevent the transgression of the surgical device beyond the surgical limitations (col. 32, lines 1-7).

Taylor et al. teach the limitations as discussed above but fail to explicitly teach an indication of scalar distance by generating an output wrench when the tool intrudes on the virtual cutting boundary. However, in the same field of endeavor, Neimeyer teach providing an indication by generating an output wrench when the tool intrudes on the virtual cutting boundary (col. 4, line 54 - col. 5, line 15). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to include an indication of scalar distance by generating an output wrench when the tool intrudes on

the virtual cutting boundary in order to enhance the connection to the system operator (for motivation see col. 4, lines 54-59).

Taylor et al. teach the limitations as discussed above but fail to explicitly teach defining a virtual cutting boundary with sharp edges and maintaining the surgical cutting tool while removing tissue. However, Taylor et al. do teach the haptic device having brakes to limit movement (abstract). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to utilize the haptic device to limit the movement in a scenario where sharp edges would normally impede a surgical operation (for motivation see abstract). Furthermore, operating in such a scenario is considered a design choice that is dependent on the particular area of the patient being operated on and the procedure being conducted (i.e. the skull as shown in fig. 6 of Taylor et al.).

Regarding **claims 15 and 46**, Taylor et al. teach the step of using tactile feedback while positioning a surgical instrument (col. 8, lines 29-30).

Regarding **claims 16 and 47**, Taylor et al. teach providing a vibration as an indicator in order to assist the surgeon in position the surgical instrument (Taylor et al., col. 8, lines 30-31).

Regarding **claims 32-35, 40, 42, 43, 48, 66, 67, and 70**, the system taught by Taylor et al. is fully capable of performing all the functional limitations recited in the claims.

Regarding **claims 6, 7, and 36-38**, Taylor et al. and Niemeyer et al. teach the limitations as discussed above but fail to explicitly teach the location of the display.

However, providing the display with a haptics/tactile device is well known to those skilled in the art. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to include integrating the display with a haptic device in order for the operator to easily watch the updated distance while controlling the tool. Furthermore, such a modification would be considered a step of making integral (see *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965)).

7. **Claims 8 and 39** are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. in view of Niemeyer et al., and further in view of Sumanaweera et al. (U.S. 6,443,894 B1). Taylor et al. and Niemeyer et al. teach the limitations as discussed above but fail to explicitly teach using color as a visual indicator. However, in the field of medical imaging, Sumanaweera et al. teach using color as a visual indicator (col. 13, lines 48-52). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to use color as a function of distance as the visual indicator in order to alert the user of the distance between the tool and the target (for motivation see (col. 13, lines 50-52, "color is assigned for different distances")).

8. **Claims 21-24 25-27, 30, 49, 52-55, 57, 58, 61-64, 71, 72, and 74** are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. in view of Niemeyer et al., and further in view of Wodicka et al. (U.S. 5,445,144).

Regarding **claims 21, 22, 25-27, 30, 49, 52-54, 57, 58, 61-64, 71, 72, and 74**, Taylor et al. and Niemeyer et al. teach the limitations as discussed above but fail to

explicitly teach an audio alert based on distance. However, in the field of medical positioning, Wodicka et al. teach using audio alerts based on distance (col. 14, lines 42-45). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to use an audio alert in order to alert the user of a distance or position status of the tool (for motivation see col. 14, lines 42-45).

Regarding **claims 23, 24, and 55**, Taylor et al., Niemeyer et al., and Wodicka et al. teach the limitations as discussed above but fail to explicitly teach the positioning of the audio alert system. However, providing the alert system as integrated with a haptics/tactile device is well known to those skilled in the art. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to include integrating the display with a haptic device in order for the operator to easily hear the updated distance while controlling the tool. Furthermore, such a modification would be considered a step of making integral (see *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965)).

Response to Arguments

9. Applicant's arguments filed 11/13/2009 have been fully considered but they are not persuasive.

Regarding Applicants' arguments with respect to claim 1, Applicants argue that "Taylor neither discloses nor suggests wherein the tool is coupled to the haptic device, much less an interactive haptic device where the surgeon can grasp and the[n] move the haptic device in order to properly position and move the tool." (page 17, second

paragraph, Arguments). Examiner first quotes claim 1 of the instant application: "tracking a position of a manually manipulatable tool mechanically coupled to a haptic device as a surgeon manually manipulates the tool;" Examiner now points to col. 15, lines 8-35 and col. 16, lines 34-67, where Taylor teaches that the fine and course motion manipulators are manually movable. If the surgeon chooses to manually move the fine or course motion manipulator, then that would mean the tool is therefore also being moved manually. Examiner would like to also point out that neither claim 1 nor the arguments (page 17, second paragraph) effectively conveys a concept different from what Taylor already teaches. The arguments only express the procedure of grasping and moving the haptic device, but not grasping the tool directly. Therefore, there is no difference between the argued invention, claimed invention, and the previously cited section of Taylor.

Applicants argue that "neither Taylor nor Neimeyer teach or fairly suggest removing tissue from a curved anatomical object while maintaining sharp edges." (page 17, paragraph 4, Arguments). Examiner directs Applicants' attention to the rejection provided above, which has been modified to address the limitation.

Regarding Applicants' arguments with respect to claim 15, Examiner directs Applicants' attention to the response to Applicants' arguments with respect to claim 1 above. Similarly, regarding the arguments made on page 18, paragraph 3, Examiner directs Applicants' attention to the response to Applicants' arguments with respect to claim 1 above.

Applicants argue that neither Taylor nor Niemeyer teach "mechanically coupling the tool to the haptic device" (page 18, paragraphs 1, 2, and 5). Examiner notes that Taylor et al. at least alone teaches this aspect by teaching a clamp which directly connects to a surgical instrument (see fig. 1a, item 117). Examiner notes that Applicants have not any rationale for disputing the prior art's teaching of this limitation.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELMER CHAO whose telephone number is (571)272-0674. The examiner can normally be reached on Mon-Thurs 11am-9pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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